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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/815,127	03/31/2004	Ashish A. Patel	G-33712P1	9219

1095 7590 04/17/2009

NOVARTIS
CORPORATE INTELLECTUAL PROPERTY
ONE HEALTH PLAZA 104/3
EAST HANOVER, NJ 07936-1080

EXAMINER	
PURDY, KYLE A	

ART UNIT	PAPER NUMBER
1611	

MAIL DATE	DELIVERY MODE
04/17/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/815,127	PATEL ET AL.	
	Examiner	Art Unit	
	Kyle Purdy	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 January 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8,10,12-16 and 18-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8, 10, 12-16 and 18-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application

1. The Examiner acknowledges receipt of the amendments filed on 01/30/2009 wherein claims 1, 18, 27 and 31 have been amended.

2. Claims 1-8, 10, 12-16 and 18-32 are presented for examination on the merits. The following rejections are made.

Response to Applicants' Arguments

3. Applicants arguments filed 01/30/2009 regarding the rejection of claims 1-8, 10, 12, 13, 16 and 18-29 made by the Examiner under 35 USC 103(a) over MacLaren et al. (US 6039974) in view of Uemura et al. (US 4695467) and Stainforth et al. (US 5858412) have been fully considered but they are not found persuasive.

4. The rejection of claims 1-, 10, 12, 13, 16 and 18-29 made by the examiner under 35 USC 103(A) is **MAINTAINED** for the reasons of record in the office action mailed on 10/30/2008.

5. In regards to the 103(a) rejection, Applicant asserts the following:

A) The claims, as currently amended, require including a wax in an amount of 10-30% by weight of the first discrete portion. This amount is half of what MacLaren teaches. The teaching of Uemura does not remedy MacLarens teaching away; and

B) There is no motivation from the provided references that would motivate an ordinary person to formulate a sustained release tablet comprising both ethylcellulose and hydroxypropyl methylcellulose in the presently claimed amounts.

6. In response to A, the Examiner acknowledges that MacLaren teaches using wax in an amount about twice from what is currently being claimed. However, the range presently claimed

is still obvious in view of the applied art. MacLaren is directed to a bilayer tablet comprising a drug containing sustained release portion, this portion contains wax. Any person of ordinary skill in the art would look to the art for other sustained release formulations which may be combined with MacLaren with a reasonable expectation for success in arriving at a product exhibiting sustained release properties. Uemura is a general teaching directed to formulating sustained release tablets. It's taught that the tablet is to comprise a wax such that the resultant tablet is easily disintegrable, as well controls the rate of drug release. Additionally, the amount of wax is dependent upon the desired properties of the drugs release rate. Contrary to Applicants assertion that Uemura only teaches including wax in Example 3, Uemura actually requires wax in their sustained release compositions. See column 4, lines 1-25. Here, Uemura teaches preferred wax amounts for the sustained release portion range from 30-55% by weight of the tablet. Thus, while it's true that MacLaren teaches using wax in an amount greater than presently claimed, the art would readily suggest to any person of skill in the art that the amount of wax is totally adjustable based upon the desired results and properties for the final release product. Moreover, because each of the references are directed to similar fields of endeavor (sustained release tablets), it would have been quite obvious to combine them in order to form a third composition to be useful for the very same purpose, with a reasonable expectation in arriving at a product with similar properties. Applicants argument is not found persuasive.

7. In response to assertion B, the Examiner respectfully disagrees. MacLaren teaches that the sustained release portion may comprise additional ingredients such as binders and fillers. As MacLaren fails to specifically mention what they include, an ordinary skilled person would be motivated to search the art to find other sustained release compositions comprising such agents,

so that appropriate modifications and improvements could be made to McLarens tablet. Uemura teaches that their sustained release tablet is to comprise water soluble polymers in a preferable amount of 5-30% by weight (see column 3, lines 30-50). Exemplified agents include cellulose derivates such as hydroxypropyl methylcellulose and hydroxypropyl cellulose. It's taught that these agents are added to modify the rate of drug release as well as aid in solubilizing the agent in solution. Stainforth is directed to sustained release tablet compositions. Stainforth teaches that a useful carrier for sustained-release matrix compositions include cellulose derivatives such as ethylcellulose. It's taught hat ethylcellulose may be included into the composition in an amount anywhere between 1-80% by weight of the tablet, depending upon the desired properties for that tablet. Therefore, one would have been motivated to include both hydroxypropyl methylcellulose and ehtylcellulose in the amount presently claimed with a reasonable expectation for success in arriving at a sustained release portion for the bilayer tablet of MacLaren. Applicants arguments are not found persuasive.

8. Applicants arguments filed 01/30/2009 regarding the rejection of claim 30 made by the Examiner under 35 USC 103(a) over MacLaren in view of Uemura, Stainforth and Okada et al. (US 5164193) have been fully considered but they are not found persuasive.

9. The rejection of claim 30 made by the examiner under 35 USC 103(a) is **MAINTAINED** for the reasons of record in the office action mailed on 10/30/2008.

10. In regards to the 103(a) rejection, Applicant asserts the following:

C) The claims, as currently amended, require including a wax in an amount of 10-30% by weight of the first discrete portion. This amount is half of what MacLaren teaches. The teaching of Uemura does not remedy MacLarens teaching away; and

D) There is no motivation from the provided references that would motivate an ordinary person to formulate a sustained release tablet comprising both ethylcellulose and hydroxypropyl methylcellulose in the presently claimed amounts.

11. In response to assertion C, Applicant is directed to the Examiners response to assertion A above.

12. In response to assertion D, Applicant is directed to the Examiners response to assertion B above.

13. Applicants arguments filed 01/30/2009 regarding the rejection of claim 14, 15 and 31 made by the Examiner under 35 USC 103(a) over MacLaren in view of Uemura, Stainforth and Bertelsen et al. (US 6713089) have been fully considered but they are not found persuasive.

14. The rejection of claims 14, 15 and 31 made by the examiner under 35 USC 103(a) is **MAINTAINED** for the reasons of record in the office action mailed on 10/30/2008.

15. In regards to the 103(a) rejection, Applicant asserts the following:

E) The claims, as currently amended, require including a wax in an amount of 10-30% by weight of the first discrete portion. This amount is half of what MacLaren teaches. The teaching of Uemura does not remedy MacLarens teaching away; and

F) There is no motivation from the provided references that would motivate an ordinary person to formulate a sustained release tablet comprising both ethylcellulose and hydroxypropyl methylcellulose in the presently claimed amounts.

16. In response to assertion E, Applicant is directed to the Examiners response to assertion A above.

17. In response to assertion F, Applicant is directed to the Examiners response to assertion B above.

18. Applicants arguments filed 01/30/2009 regarding the rejection of claim 32 made by the Examiner under 35 USC 103(a) over MacLaren in view of Uemura, Stainforth Okada and Bertlesen have been fully considered but they are not found persuasive.

19. The rejection of claim 32 made by the examiner under 35 USC 103(a) is **MAINTAINED** for the reasons of record in the office action mailed on 10/30/2008.

20. In regards to the 103(a) rejection, Applicant asserts the following:

G) The claims, as currently amended, require including a wax in an amount of 10-30% by weight of the first discrete portion. This amount is half of what MacLaren teaches. The teaching of Uemura does not remedy MacLarens teaching away; and

H) There is no motivation from the provided references that would motivate an ordinary person to formulate a sustained release tablet comprising both ethylcellulose and hydroxypropyl methylcellulose in the presently claimed amounts.

21. In response to assertion G, Applicant is directed to the Examiners response to assertion A above.

22. In response to assertion H, Applicant is directed to the Examiners response to assertion B above.

Claim Rejections - 35 USC § 103

23. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

24. **Claims 1-8, 10, 12-13, 16 and 18-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over MacLaren et al. (US 6039974; of record) in view of Uemura et al. (US 4695467; of record) and Stainforth et al. (US 5858412; of record)**.

25. MacLaren teaches a pharmaceutical composition that is a combination of piperidinoalkanol-decongestant wherein the composition is in the form of a bilayer tablet comprising two discrete zones (see abstract). It is taught formulation A is sustained release portion which comprises a decongestant (i.e. sympathomimetic drug; see instant claims 1 and 27), specifically that of pseudoephedrine which is present in an amount of 120 mg (see column 2, lines 32-40 and Table 1; see instant claims 2, 3 and 29). Table 1 teaches that the sympathomimetic drug containing layer contains a carnuba wax, stearic acid and silicon dioxide.

26. Formulation B is an immediate release portion which comprises a piperidinoalkanol compound, specifically that of fexofenadine which is present in an amount of 60 mg (see column 2, lines 32-40 and Table 1; see instant claims 1, 4-7 and 29). Fexofenadine is a widely used antihistamine, antiallergic agents and bronchodilator. Table 5 teaches that the fexofenadine containing portion of the tablet comprises among other ingredients a diluent (or filler), a disintegrant and a lubricant which are microcrystalline cellulose (functionally equivalent to lactose (see column 11, line 35)) from about 27% and 73%, croscarmellose sodium from about

0.25% and 6.0% by weight and magnesium stearate from about 0.25% to about 2.00%, respectively (see abstract; see instant claims 1, 12, 13, 16, 18, 24, 25 and 26).

27. It is also taught that Formulation A and Formulation B may contain excipients which are commonly used in the art such as binders, diluents, lubricants, glidants, disintegrants, etc.. It is taught that lubricant may be magnesium stearate and the diluent (or filler) may be lactose (see column 11, lines 20-40; see instant claim 9). MacLaren also teaches that the bilayertblet may be coated (see Table 1).

28. Maclaren fails to teach the sustained release portion, Formulation A, as comprising ethylcellulose from about 10% to about 35% by weight. Maclaren also fails to teach the composition as comprising a filler from about 5% to about 20%, a cellulose binder at a weight percentage from about 10% to about 60%, and from about 10% to about 30% of a wax and a lubricant from about 0.5% to about 2%.

29. The teaching of Uemura is directed to a sustained release tablet formulation. The sustained release formulation comprises granules comprising a drug, a disintegrating agent and a water soluble polymer (see abstract). Example 3 teaches a formulation for a sustained release formulation which comprises a drug, low substituted hydroxypropyl cellulose (binder) at a weight percentage of 23%, hydroxypropyl methylcellulose (binder), lactose (filler) at a weight percentage of 7.5%, carnuba wax (wax) at a weight percent of 25% and magnesium stearate (lubricant) at a weight percent of 0.2% (see instant claims 1 and 18-22). Uemura teaches preferred wax amounts for the sustained release portion range from 30-55% by weight of the tablet (see column 4, lines 1-25) and aids in modifying the rate of release .

30. Stainforth is drawn to sustained release formulations utilizing pharmaceutical excipients having improved compressibility. It is disclosed that suitable materials for use in sustained release tablet formulations includes alkylcelluloses such as ethylcellulose (see column 16, lines 50-55). It is taught that the tablet will preferably contain the alkyl cellulose between from about 1 to about 80% by weight of the sustained release dosage form (see column 18, line 20; see instant claims 1, 18 and 27).

31. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have combined the teachings of MacLaren, Uemura and Stainforth with a reasonable expectation for success in arriving at a bilayer tablet comprising two discrete zones wherein discrete zone A is a sustained release zone which comprises 120 mg of pseudoephedrine and a filler (lactose), a cellulose binder (hydropropyl methylcellulose), ethylcellulose, between 2% to about 50% a wax (carnuba) and a lubricant (magnesium stearate) and wherein discrete zone B is an immediate release zone which comprises 60 mg of fexofenadine, a sugar (lactose), disintegrant (croscarmellose sodium) and a lubricant (magnesium stearate) at the required weight percentages (see above). The significance of MacLaren is that it teaches the major inventive concept, a bilayer tablet in which one layer is a sustained release layer for psuedoephedrine and the other layer is an immediate release layer for fexofenadine wherein the fexfenadine layer further comprises a cellulose diluent, a disintegrant and a lubricant. Moreover, MacLaren teaches that the cellulose diluent (microcrystalline cellulose) is functionally equivalent to lactose (see above) as well as indicates that both portions of the tablet may include excipients such as lactose and magnesium stearate. MacLaren fails to teach portion A of the tablet comprising a filler, a cellulose binder, ethylcellulose, a wax and a lubricant at the specified weight percentages (see

above). With respect to the inclusion of a wax from about 2 to 50% and the inclusion of a cellulose binder, a lubricant and a filler, the teaching of Uemura cures these deficiencies. Uemura teaches a formulation for a sustained release tablet comprising a cellulose binder, specifically low-substituted hydroxypropyl cellulose at a weight percentage of 23%, lactose at a weight percentage of 7.5%, a wax at a weight percentage of about 25%. With respect to the inclusion of ethylcelluose, the teaching of Stainforth cures this deficiency. Stainforth states that ethylcellulose is a commonly used carrier matrix in sustained release tablet formulations and can be used between 1-80 weight %. As all of these references are within the same general field of endeavor (i.e. adjusting the rate of release from a solid dosage form), one would have been motivated to combine the references and arrive at a product possessing the instantly claimed properties. It should be noted that the excipients which Applicant employs in their dosage forms are commonly used in tablet formulations (both immediate and sustained release formulations), and it would have been obvious to one ordinarily skilled in the art to adjust and vary the amounts of the ingredients in the composition to arrive at a dosage form with the greatest therapeutic properties. Therefore, the invention as a whole is *prima facie* obvious to one ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in absence of evidence to the contrary.

32. **Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over MacLaren et al. (US 6039974; of record) in view of Uemura et al. (US 4695467; of record), Stainforth et al. (US 5858412; of record) and Okada et al. (US 5164193; of record)**.

33. Maclaren, Uemura and Stainforth are relied upon for disclosure described in the rejection of claim 1-8, 10, 11-13, 16 and 18-29 under 35 U.S.C. 103(a).

34. MacLaren, Uemura and Stainforth fail to teach the sustained release portion of the bilayer tablet (A) as comprising between 2% to about 50% stearyl alcohol.

35. Okada cures this deficiency. Okada is drawn to a sustained release tablet which comprises an oil or waxy component (see abstract). Many oily and waxy components are disclosed (see column 2 and column 3) such as carnuba wax and stearyl alcohol. It is disclosed that stearyl alcohol is a preferred alcohol (see column 3, line 20). Moreover, it is taught that in order to ensure the effect of the present invention that the oil component bet present a weight percentage of 5.0% and greater (see column 4, line 10).

36. Therefore, it would have been obvious to one ordinarily skilled in the art at the time the invention was made to combine the teachings of MacLaren, Uemura, Stainforth and Okada with a reasonable expectation for success in arriving at a bilayer tablet in which the sustained release (A) portion comprises lactose (see above), hydroxypropylmethylcellulose (see above), ethylcellulose (see above), stearyl alcohol at about 5.0 wt. % or more and magnesium stearate (see above). The significance of Okada is that it teaches stearyl alcohol as being a particularly preferred and a useful oily component for implementation in a sustained release formulation. Moreover, it is taught that carnuba wax is functionally equivalent to stearyl alcohol. One of ordinary skill in the art would be motivated to substitute one for the other with a reasonable expectation for success in a product having sustained release properties. Therefore, a composition sustained release layer of a bilayer tablet comprising about 5% stearyl alcohol is

prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in absence of evidence to the contrary.

37. **Claims 14, 15 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over MacLaren et al. (US 6039974; of record) in view of Uemura et al. (US 4695467; of record), Stainforth et al. (US 5858412; of record) and Bertelsen et al. (US 6713089; of record).**

38. Maclaren, Uemura and Stainforth are relied upon for disclosure described in the rejection of claim 1-8, 10, 11-13, 16 and 18-29 under 35 U.S.C. 103(a).

39. MacLaren, Uemura and Stainforth fails to teach the immediate release portion of the bilayer tablet (B) as comprising the disintegrant low-substituted hydroxypropyl cellulose wherein the low-substituted hydroxypropyl cellulose may be selected from a wide range of species with varying hydroxypropy content and average particle size.

40. Bertelsen is drawn to rapid release formulations. It is disclosed that low-substituted hydroxypropyl cellulose is a useful disintegrant (see column 14, lines 35-55; see instant claim 14). Exemplified low-substituted hydroxycellulose include LH-20 and LH-21 (see column 14, line 55; see instant claim 15).

41. Therefore, it would have been obvious to one ordinarily skilled in the art at the time the invention was made to combine the teachings of MacLaren, Uemura, Stainforth and Bertelsen with a reasonable expectation for success in arriving at a bilayer tablet in which the immediate release portion (B) comprises the disintegrant low-substituted hydroxypropyl cellulose (i.e. LH-20 or LH-21), a filler (lactose, see above) and a lubricant (magnesium stearate, see above). The significance of Bertelsen is that it teaches the inclusion of low-substituted hydroxypropyl

cellulose in a rapid release formulation which has a disintegrant function. Thus, one would have been motivated to use a low-substituted hydroxypropyl cellulose compound in a rapid release composition or rapid release portion of a bilayer tablet with a reasonable expectation for success for that composition to possess rapid release properties. Therefore, a bilayer tablet which comprises a immediate release layer comprising low-substituted hydroxypropyl cellulose is *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in absence of evidence to the contrary.

42. **Claim 32 is rejected under 35 U.S.C. 103(a) as being unpatentable over MacLaren et al. (US 6039974; of record) in view of Uemura et al. (US 4695467; of record), Stainforth et al. (US 5858412; of record), Okada et al. (US 5164193; of record) and Bertelsen et al. (US 6713089; of record)**.

43. Maclaren, Uemura, Stainforth and Okada are relied upon for disclosure described in the rejection of claim 30 under 35 U.S.C. 103(a).

44. MacLaren, Uemura, Stainforth and Okada fail to teach the immediate release portion of the bilayer tablet (B) as comprising as the disintegrant low-substituted hydroxypropyl cellulose.

45. Bertelsen is drawn to rapid release formulations. It is disclosed that low-substituted hydroxypropyl cellulose is a useful disintegrant (see column 14, lines 35-55; see instant claim 14). Exemplified low-substituted hydroxycellulose include LH-20 and LH-21 (see column 14, line 55; see instant claim 32).

46. Therefore, it would have been obvious to one ordinarily skilled in the art at the time the invention was made to combine the teachings of MacLaren, Uemura, Stainforth, Okada and

Bertelsen with a reasonable expectation for success in arriving at a bilayer tablet in which the immediate release portion (B) comprises as the disintegrant low-substituted hydroxypropyl cellulose. The significance of Bertelsen is that it teaches the inclusion of low-substituted hydroxypropyl cellulose in a rapid release formulation which has a disintegrant function. Thus, one would have been motivated to use a low-substituted hydroxypropyl cellulose compound in a rapid release composition or rapid release portion of a bilayer tablet because Maclaren specifically stipulates for the inclusion of a disintegrant component. One would be motivated to scour the art in search of compounds capable of performing Maclarens intended purpose. Therefore, a bilayer tablet which comprises a immediate release layer comprising low-substituted hydroxypropyl cellulose is *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in absence of evidence to the contrary.

Conclusion

47. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

48. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

49. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kyle A. Purdy whose telephone number is 571-270-3504. The examiner can normally be reached from 9AM to 5PM.

50. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau, can be reached on 571-272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

51. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Kyle Purdy/
Examiner, Art Unit 1611
April 15, 2009

/David J Blanchard/
Primary Examiner, Art Unit 1643